Food Safety Legislation

Elizabeth Barr Fawell

October 14, 2009

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Agenda

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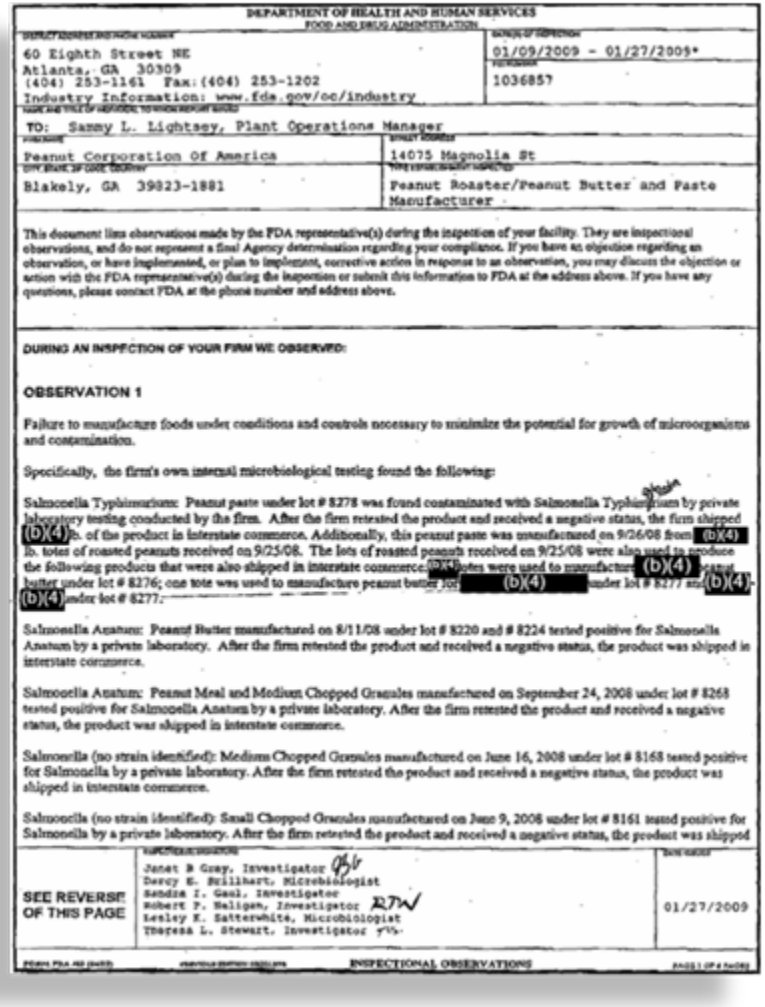
- **How we got here**
- **Overview of H.R. 2749 The Food Safety Enhancement Act of 2009**
  - **New responsibilities for companies**
  - **Increased oversight of imports**
  - **New enforcement authorities**
  - **Fees**
- **What's next**
- **Key Differences in S. 510**

How We Got Here

- **Series of high profile food safety outbreaks**
- **Food manufacturing standards in the FFDCA date back to 1906**
- **Strong support from the Obama Administration**



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

60 Eighth Street NE
Atlanta, GA 30309
(404) 253-1161 Fax:(404) 253-1202
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION: 01/09/2009 - 01/27/2009*
FEI NUMBER: 1036857

TO: Sammy L. Lightsey, Plant Operations Manager

FIRM NAME: Peanut Corporation Of America
STREET ADDRESS: 14075 Magnolia St
CITY, STATE AND ZIP CODE OF FACILITY: Blakely, GA 39823-1881
TYPE ESTABLISHMENT INSPECTED: Peanut Roaster/Peanut Butter and Paste Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Failure to manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

Specifically, the firm's own internal microbiological testing found the following:

Salmonella Typhimurium: Peanut paste under lot # 8278 was found contaminated with Salmonella Typhimurium by private laboratory testing conducted by the firm. After the firm retested the product and received a negative status, the firm shipped (b)(4) lb. of the product in interstate commerce. Additionally, this peanut paste was manufactured on 9/26/08 from (b)(4) lb. totes of roasted peanuts received on 9/25/08. The lots of roasted peanuts received on 9/25/08 were also used to produce the following products that were also shipped in interstate commerce: (b)(4) totes were used to manufacture (b)(4) peanut butter under lot # 8276; one tote was used to manufacture peanut butter lot (b)(4) under lot # 8277 and (b)(4) under lot # 8277.

Salmonella Anatum: Peanut Butter manufactured on 8/11/08 under lot # 8220 and # 8224 tested positive for Salmonella Anatum by a private laboratory. After the firm retested the product and received a negative status, the product was shipped in interstate commerce.

Salmonella Anatum: Peanut Meal and Medium Chopped Granules manufactured on September 24, 2008 under lot # 8268 tested positive for Salmonella Anatum by a private laboratory. After the firm retested the product and received a negative status, the product was shipped in interstate commerce.

Salmonella (no strain identified): Medium Chopped Granules manufactured on June 16, 2008 under lot # 8168 tested positive for Salmonella by a private laboratory. After the firm retested the product and received a negative status, the product was shipped in interstate commerce.

Salmonella (no strain identified): Small Chopped Granules manufactured on June 9, 2008 under lot # 8161 tested positive for Salmonella by a private laboratory. After the firm retested the product and received a negative status, the product was shipped

SEE REVERSE OF THIS PAGE

Janet B Gray, Investigator
Darcy E. Billhart, Microbiologist
Sandra I. Gaul, Investigator
Robert P. Haligan, Investigator
Lesley K. Satterwhite, Microbiologist
Theresa L. Stewart, Investigator

01/27/2009

INSPECTIONAL OBSERVATIONS

What's Coming

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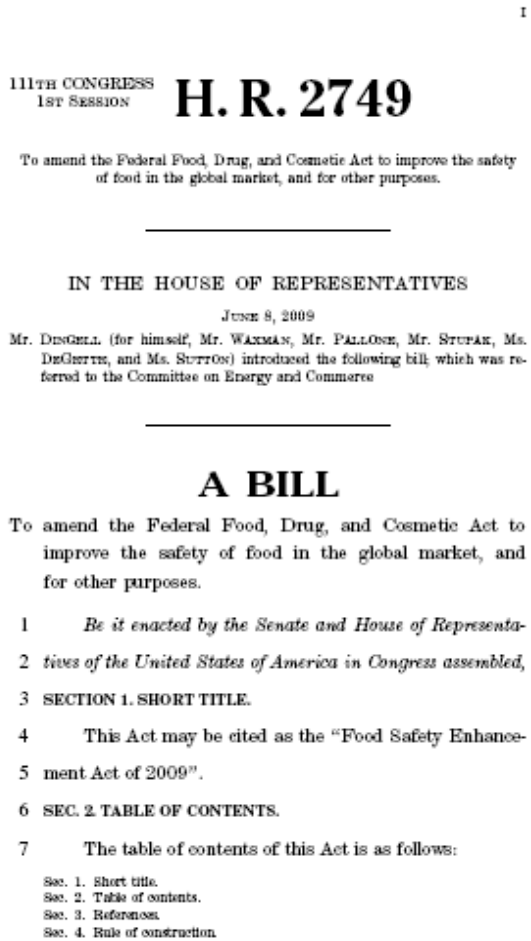
- **July 2009, the U.S. House of Representatives passed H.R. 2749, the Food Safety Enhancement Act of 2009**
  - **New responsibilities for companies**
  - **Increased oversight of imports**
  - **New enforcement authorities**
  - **Fees**

Food Industry Responsibilities

- **Impacting daily operations**
  - **Food Safety Plans**
  - **Food Defense Plans**
  - **Performance standards**
  - **Full records access**
  - **Traceability**
  - **Reporting requirements**
- **Not to be forgotten**
  - **Annual registration**
  - **Risk-based inspections**
  - **Safety standards for fruits, vegetables, and nuts**
  - **COOL**



I

111TH CONGRESS
1ST SESSION

H. R. 2749

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 8, 2009

Mr. DINGELL (for himself, Mr. WAXMAN, Mr. PALLONE, Mr. STUPAK, Ms. DEGETTE, and Ms. SUTTON) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food in the global market, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Food Safety Enhancement Act of 2009".

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents.
Sec. 3. References.
Sec. 4. Rule of construction.

Food Safety Plans

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- Conduct hazard analysis
- Identify and implement preventive controls
  - To prevent, eliminate, or reduce hazards to an acceptable level
  - Those controls a person knowledgeable about safe manufacturing, processing, packing, transporting, holding of food would employ
  - Consistent with current scientific understanding
- Validate food safety plan
- Monitor and verify performance
- Take corrective and preventive actions as needed
- Keep records
- FDA can establish preventive controls by product type

Food Defense Plans

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- **Identify hazards that may be intentionally introduced**
- **Implement preventive measures to minimize risk of intentional contamination**
  - **Processing security**
  - **Cybersecurity**
  - **Material security (ingredients, finished product, packaging)**
  - **Personnel security**
  - **Storage security**
  - **Shipping and receiving security**
  - **Utility security**
- **Check that measures are in place and working; periodically test plan**
- **Maintain records of checks, corrective actions, assessment activities**

Oversight of Imports

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- **Foreign facilities subject to all the same requirements as U.S-based facilities**
- **FDA authority to require third party certification for food safety-related reason**
- **Accredited laboratory must be used for import testing**
- **Importers and customs brokers required to register**
- **Good importer practices**
  - **Including supply chain verification procedures**
- **Tighter control over import entry filings**
- **Expedited entry at border if safety and security guidelines met**

Enforcement Authorities

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- Civil money penalties
- Increased criminal penalties
- Suspension of registration
- Mandatory recall
- Quarantine
- Expanded administrative detention authority
- Subpoena power
- Prohibition on false or misleading reports
- Prohibition on delaying or refusing an inspection

Fees

- **Registration Fee**
  - **$500 per facility**
  - **$175,000 cap per company**
- **Registration fee for importers (but not customs brokers)**
  - **$500**
- **Reimbursement to FDA for**
  - **Re-inspections**
  - **Recall**
- **Export certificates**

Next Steps

- **Senate expected to take up a bill this fall**
- **President Obama will likely sign**

Key Differences in S. 510

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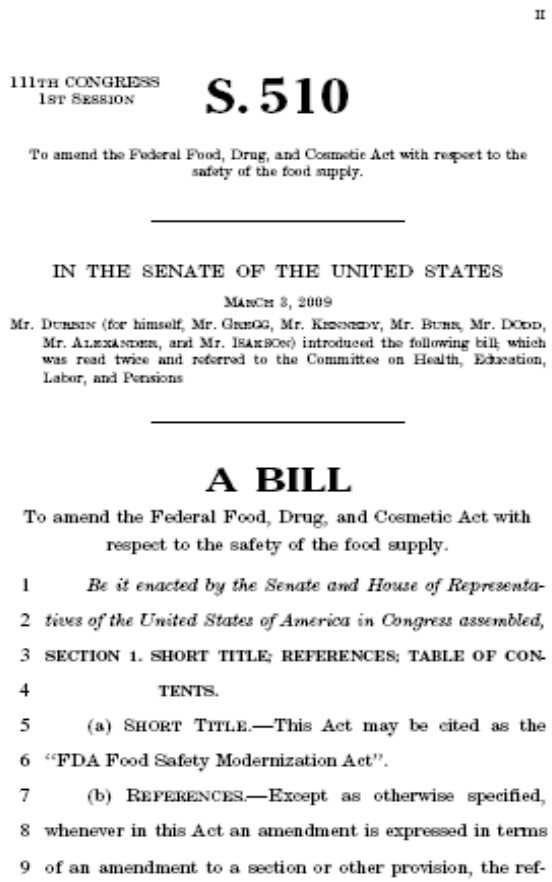
- Traceability
- Records Access
- Mandatory recall authority
- Foreign supplier verification program
- Third party certification
- No registration fee
- Fewer enforcement authorities
- No COOL



II

111TH CONGRESS
1ST SESSION

S. 510

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

IN THE SENATE OF THE UNITED STATES

MARCH 3, 2009

Mr. DURBIN (for himself, Mr. GREGG, Mr. KENNEDY, Mr. BURR, Mr. DODD, Mr. ALEXANDER, and Mr. ISAKSON) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "FDA Food Safety Modernization Act".

(b) REFERENCES.—Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the ref-

Down the Road

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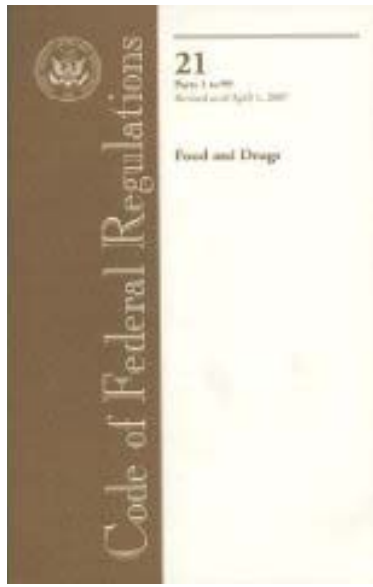
- **Various effective dates for different provisions**
- **Some provisions require FDA fact-finding and new regulations**
- **Longer implementation time for small and very small businesses**



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